DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

MAY 15 2000

WARNING LETTER
ONPLDS 02-00

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John Ferolito
President
Ferolito, Vultaggio & Sons, Inc.
5 Dakota Drive
Suite 205
Lake Success, New York 11042

Dear Mr. Ferolito:

The Food and Drug Administration (FDA) has reviewed the label for your "Arizona Rx Stress Relief Elixir." Our review reveals that this label causes the product to be in violation of section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

This product is misbranded within the meaning of section 403(r)(1)(A) of the Act in that the label bears nutrient content claims that are not authorized by regulation or the Act or are not consistent with an authorizing regulation. The claims include "...ENHANCED WITH PANAX GINSENG•KAVA-KAVA•CHAMOMILE•VALERIAN ..." and "...FORTIFIED WITH ...MINERALS." In the context used on this label the term "enhanced" is considered to be an unauthorized synonym for "added."

FDA has defined the nutrient content claim "added" in 21 CFR 101.54(e). "Added" can be used to describe the level of protein, vitamins, minerals, dietary fiber, or potassium, nutrients for which there are established reference values. There are no established reference values for Panax Ginseng, Kava-Kava, Chamomile or Valerian. Since Panax Ginseng, Kava-Kava, Chamomile and Valerian are not one of the substances included in 21 CFR 101.54(e), the claim "ENHANCED WITH PANAX GINSENG•KAVA-KAVA•CHAMOMILE•VALERIAN" is not authorized. Because the claim is not authorized as a nutrient content claim by regulation or by the Act, the claim misbrands the product.

The claim "fortified with ... minerals" is not consistent with the regulation governing use of the claim "fortified." "Fortified" may be used on the label of foods, in part, to describe the level of specific minerals provided that the food contains at least 10 percent more of the RDI for each mineral per reference amount customarily consumed than an appropriate

reference food (21 CFR 101.54(e)). The reference amount customarily consumed for a beverage is 240 ml. The only mineral declared on the product label is calcium and the nutrition information states that calcium is present at a level of only 1% of the RDI per 8 fluid ounces. Because the use of the claim is not consistent with the regulation governing the term "fortified," the claim misbrands the product.

The product is further misbranded within the meaning of section 403(a)(1) of the Act. The label bears the "Rx" symbol in several locations and also bears statements, such as, "RX STRESS," "RELIEF ELIXIR," "A SAFE AND CERTAIN REMEDY" and "Rx STRESS REMEDY" that in the context of the labeling as a whole suggest that this is a prescription product. If your intention is to market this product as a food, the label must be revised so that the prescription symbols and the other phrases and terms that suggest this product is a Rx drug are removed from this label. In addition, the statement of identity must appear as one of the principal features on the principal display panel in accordance with the requirements in 21 CFR 101.3.

The above violations are not meant to be an all inclusive list of deficiencies on your product labels. It is your responsibility to assure that all of your products are labeled in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

We also point out that any ingredient intentionally added to a conventional food such as this beverage or any of your other products must be used in accordance with a food additive regulation, unless it is generally recognized as safe (GRAS) among qualified experts for its intended use. The use of a food ingredient that is neither GRAS nor an approved food additive causes a food to be adulterated under section 402(a)(2)(C) of the Act. You must assure that the ingredients used in your products are either GRAS for their intended use or used in accordance with a food additive regulation.

Please notify this office within 15 working days of receipt of this letter, of the specific steps you have taken or plan to take to correct the noted violations. Copies of revised labels for the products should also be submitted. If corrective actions cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

You should direct your written reply to me at the Food and Drug Administration, Office of Nutritional Products, Labeling, and Dietary Supplements, 200 C Street, S.W., Washington, D.C. 20204.

Sincerely yours,

/S/

John B. Foret
Director
Division of Compliance
and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition